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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/884,319	06/18/2001	James Graham	22058-568 DIV1ACON	4845

7590 03/18/2004

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EXAMINER	
MERTZ, PREMA MARIA	
ART UNIT	**PAPER NUMBER**
1646	

DATE MAILED: 03/18/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/884,319	GRAHAM ET AL.	
	Examiner	Art Unit	
	Prema M Mertz	1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *09 January 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *17 and 26-38* is/are pending in the application.

4a) Of the above claim(s) *27-29* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *17, 26, 30-38* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

13)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

a) ☐ The translation of the foreign language provisional application has been received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Election/Restriction

1. Applicant's election with traverse of Group 1 (claims 17, 26, 30-38) on 1/9/2004 is acknowledged. The traversal is on the ground(s) that the restriction is improper since the examiner has not shown why Group II (drawn to an antibody to a protein comprising the amino acid sequence set forth in SEQ ID NO:4) lacks unity with Group I (drawn to an antibody to a protein comprising the amino acid sequence set forth in SEQ ID NO:2). This argument is not found persuasive because the Examiner has cited art to demonstrate that the two Groups lack a special technical feature that is unique and is absent from the prior art.

Each of the antibodies of Groups I-II does not share a common technical feature, which is based on a common property or special technical feature not found in the prior art. These antibodies are independent and distinct chemical compounds lacking either a common structural property which distinguishes them as a group from structurally related compounds of the prior art or which provides them with a common utility, which is lacking from those prior art elements.

The first claimed invention fails to recite such a feature, since the claim recites an antibody to a polypeptide comprising" the amino acid sequence of SEQ of NO:2, which encompasses an antibody to FLAG protein which antibody is found in the prior art. The text on page 23 of the instant specification encompasses a polypeptide of SEQ ID NO:2, which can include a "tag". Because of the presence of the term "comprising" in instant claim 17, the claim encompasses any antibody which can bind to any epitope which can be expressed as a portion of a polypeptide comprising the amino acid sequence as set fourth in SEQ ID NO:2 and, therefore

the claim essentially encompasses any antibody which can bind to any polypeptide or protein comprising a "tag". Group I encompasses an antibody which binds to any antigenic peptide, including the flag epitope DYKDDDDK which was bound by the antibody of Hopp et al. (U.S. Patent 5,011,912, 4/1991) prior to the time of the instant invention. The reference discloses the antibody (column 5, lines 55-59) meeting the limitations of an antibody to a polypeptide comprising" the amino acid sequence of SEQ ID N0:2. Since the first claimed invention lacks a special technical feature, the other claimed inventions cannot share a special technical feature with the first claimed invention.

Having shown that these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their recognized divergent subject matter as defined by MPEP 808.02, the Examiner has prima facie shown a serious burden of search (see MPEP 803). Therefore, an initial requirement of restriction for examination purposes as indicated is proper. Therefore, both Groups I and II lack a special technical feature that is unique and absent from the prior art and the lack of unity set forth on 9/9/2003 is proper and is being maintained.

The Groups as delineated in the restriction requirement (9/9/2003) meet the requirements to support a lack of unity between the Groups.

The requirement is still deemed proper and is therefore made FINAL.

Claim 27-29 are withdrawn from further consideration by the examiner, as being drawn to a non-elected invention.

Specification

2. The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed i.e. a more specific title that would identify the antibody by the protein it binds to. Furthermore, all inventions are presumed novel. Therefore, it is suggested that the term "novel" be deleted from the title of the invention.

3. Applicant is reminded of the proper content of an abstract of the disclosure.

In chemical patent abstracts for compounds or compositions, the general nature of the claimed compound or composition should be given as well as its use, e.g., "The compounds are of the class of alkyl benzene sulfonyl ureas, useful as oral anti-diabetics."

Complete revision of the content of the instant abstract to include the claimed antibodies, is required on a separate sheet.

Claim Rejections - 35 USC § 101

4. 35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter or any new and useful improvement thereof, may obtain a patent therefore, subject to the conditions and requirements of this title.

Claims 17, 26, 30-38, are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

The claims embrace an antibody circulating in a host. However, since it would that applicants do not intend to claim such antibodies, amending the claims to require the hand-of-man would obviate this rejection i.e. an isolated antibody.

Claim Rejections - 35 USC § 112, first paragraph

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5a. Claims 17, 30, 32-33, 35-36, are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for an antibody to an IL-1-R intracellular ligand protein consisting of the amino acid sequence set forth in SEQ ID NO:2, does not reasonably provide enablement for an antibody to an IL-1-R intracellular ligand protein comprising the amino acid sequence of SEQ ID NO:2. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

Claim 17 is clearly a single means claim because it encompasses any antibody to any protein that exists now and in the future, irrespective of the structure of that protein. Furthermore, the claim encompasses any antibody to a fusion protein which "comprises" the amino acid sequence set forth in SEQ ID NO:2. Claim 17 is a single means claim because the specification has only provided a description for an antibody to a polypeptide of amino acid sequence set forth in SEQ ID NO:2. A single means claim, i.e., where a means recitation does not appear in combination with another recited element of means, is subject to an undue breadth rejection under 35 U.S.C. 112, first paragraph. *In re Hyatt*, 708 F.2d 712,714 - 715, 218 USPQ 195, 197 (Fed. Cir. 1983) (A single means claim which covered every conceivable means for achieving the stated purpose was held nonenabling for the scope of the claim because the specification disclosed at most only those means known to the inventor.). When claims depend

on a recited property, a fact situation comparable to Hyatt is possible, where the claim covers every conceivable structure (means) for achieving the stated property (result) while the specification discloses at most only those known to the inventor. See M.P.E.P. 2164.08(a).

Further, the instant specification does not provide an adequate description of the genus of antibody compounds encompassed by this claim. In the decision of *The Regents of the University of California v. Eli Lilly and Company,* 43 USPQ2d 1398 (CAFC 1997), the court held that:

"To fulfill the written description requirement, a patent specification must describe an invention and do so in sufficient detail that one skilled in the art can clearly conclude that "the inventor invented the claimed invention." *Lockwood v. American Airlines, Inc.*, 107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966 (1997); *In re Gosteli*, 872 F.2d 1008, 1012, 10 USPQ2d 1614, 1618 (Fed. Cir. 1989) (" [T]he description must clearly allow persons of ordinary skill in the art to recognize that [the inventor] invented what is claimed."). Thus, an applicant complies with the written description requirement "by describing the invention, with all its claimed limitations, not that which makes it obvious," and by using "such descriptive means as words, structures, figures, diagrams, formulas, etc., that set forth the claimed invention." *Lockwood*, 107 F.3d at 1572, 41 USPQ2d at 1966.

An adequate written description of a DNA, such as the cDNA of the recombinant plasmids and microorganisms of the '525 patent, "requires a precise definition, such as by structure, formula, chemical name, or physical properties," not a mere wish or plan for obtaining the claimed chemical invention. *Fiers v. Revel*, 984 F.2d 1164, 1171, 25 USPQ2d 1601, 1606 (Fed. Cir. 1993). Accordingly, "an adequate written description of a DNA requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it; what is required is a description of the DNA itself." Id. at 1170, 25 USPQ2d at 1606. The

instant specification does not provide a structural formula which is definitive of a genus of proteins to which the antibody claimed in claim 17 can bind. A patent is granted for a completed invention, not the general suggestion of an idea and how that idea might be developed into the claimed invention. In the decision of *Genentech, Inc, v. Novo Nordisk*, 42 USPQ 2d 100,(CAFC 1997), the court held that "[p]atent protection is granted in return for an enabling disclosure of an invention, not for vague intimations of general ideas that may or may not be workable" and that "[t]ossing out the mere germ of an idea does not constitute enabling disclosure". The court further stated that "when there is no disclosure of any specific starting material or of any of the conditions under which a process is to be carried out, undue experimentation is required; there is a failure to meet the enablement requirements that cannot be rectified by asserting that all the disclosure related to the process is within the skill of the art", "[i]t is the specification, not the knowledge of one skilled in the art, that must supply the novel aspects of an invention in order to constitute adequate enablement".

The instant specification is not enabling because one cannot following the guidance presented therein produce the claimed antibody to a protein comprising the amino acid sequence of SEQ ID NO:2 without first making a substantial inventive contribution.

5b. Claims 17, 30, 32-33, 35-36, are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Because of the presence of "comprising the amino acid sequence of SEQ ID NO:2" in claim 17, the instant claim encompasses an antibody which binds to an epitope that is not contained within SEQ ID NO:2. It is old and well known in the art that the portion of a protein

to which an antibody binds usually consists of no more than six to eight amino acid residues. It was also well known in the art long before the instant invention was made to express a recombinant protein as part of a fusion protein "comprising", in addition to the amino acid sequence of a desired protein, an antigenic tail such as a "FLAG epitope", a polyhistidine tail, or a "Protein A" fragment to facilitate the purification of the desired protein. The instant specification encompasses a polypeptide of amino acid sequence set forth in SEQ ID NO:2 which can include a "tag". Because of the presence of the term "comprising" in the instant claims, they encompass any antibody which can bind to any epitope which can be expressed as a portion of a polypeptide comprising the amino acid sequence as set fourth in SEQ ID NO:2 and, therefore they essentially encompass any antibody which can bind to any polypeptide or protein. The instant specification, however, does not provide a written description or the guidance needed to produce an antibody, which binds to any epitope other than an epitope, which is contained within SEQ ID NO:2 of the instant application.

Claim rejections-35 U.S.C. 112, second paragraph

6. Claims 17, 26, 30-38 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 17, 31, 34, 37 are vague and indefinite because they recite non-elected subject matter. It is suggested that to obviate this rejection, the claims be amended to delete recitation of the non-elected subject matter.

Claims 26, 30, 32-33, 35-36, 38 are rejected as vague and indefinite insofar as they depend on claim 20 for this limitation.

Claim Rejections - 35 USC § 102

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless --
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7a. Claims 17, 30, 32-33, 35, 36, are rejected under 35 U.S.C. 102(b) as being anticipated by the Hopp et al. patent (5,011,912). As explained above in paragraph 1, these claims encompass an antibody, which binds to any antigenic peptide, including the flag epitope DYKDDDDK which was bound by the antibody of Hopp et al. prior to the time of the instant invention. The reference discloses the antibody and a pharmaceutical composition comprising the antibody (column 4, lines 31-48; column 5, lines 55-59) meeting the limitations of claims 17, 30 32, 33, 35-36, a hybridoma (column 4, lines 51-68; column 5, lines 1-54), and the monoclonal antibody so produced (column 8, claims 2-4). Therefore, the antibody and monoclonal antibody of the reference anticipate instant claims 17, 30, 32-33, 35, 36.

Conclusion

No claim is allowed.

Advisory Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Prema Mertz whose telephone number is (571) 272-0876. The examiner can normally be reached on Monday-Friday from 7:00AM to 3:30PM (Eastern time).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler, can be reached on (571) 271-0871.

Official papers filed by fax should be directed to (703) 872-9306. Faxed draft or informal communications with the examiner should be directed to (571) 273-0876.

Communications via Internet e-mail regarding this application, other than those under 35 U.S.C. 132 or which otherwise require a signature, may be used by the applicant and should be addressed to [yvonne.eyler@uspto.gov].

All Internet e-mail communications will be made of record in the application file. PTO employees do not engage in Internet communications where there exists a possibility that sensitive information could be identified or exchanged unless the record includes a properly signed express waiver of the confidentiality requirements of 35 U.S.C. 122. This is more clearly

set forth in the Interim Internet Usage Policy published in the Official Gazette of the Patent and Trademark Office on February 25, 1997 at 1195 OG 89.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Prema Mertz

Prema Mertz Ph.D.
Primary Examiner
Art Unit 1646
February 9, 2004